

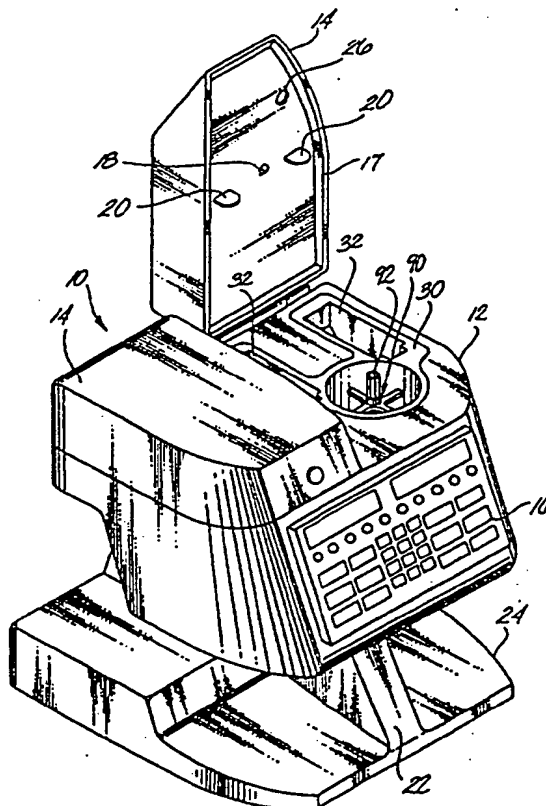
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(54) Title: AUTOMATED BONE CEMENT MIXING APPARATUS**(57) Abstract**

A motorized mixer (10) for mixing bone cement for use in attachment of prosthetics and method for using the mixer (10). The mixer comprises a mixing chamber, a liner (30) in the mixing chamber, an impeller (90) within the liner, a motor for driving the impeller (90) and programmable means (16) for regulating the operations of the motor. An impeller (90) for use in a mixer (10) for mixing bone cement having a mixing chamber and means for mixing cement within the chamber that allows the simultaneous exposure of the mixing chamber and the post-cement delivery area to a vacuum source to prevent air from being folded into the cement during mixing and post-mixing transfer as well as aiding in the ease of cement transfer from the mixing chamber to the post-mixing cement collection area.



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AUTOMATED BONE CEMENT MIXING APPARATUS

Field of the Invention

This invention relates to an apparatus and method for mixing bone cement for use in surgical procedures such as hip replacements and, more particularly, to an impeller used in such apparatus and method.

Background of the Invention

Damage to the joints of the human body, due to arthritis, other degenerative diseases or trauma, often results in the need to replace the joint with a prosthetic device. In the case of hip replacement surgery such devices include a cup which fits into the hip socket, and replaces the acetabulum, and a ball attached to a stem which fits into the femur and replaces the head of the femur. A cement is used to secure the prosthetic devices to the bone.

Currently, the cement used for such replacement is polymethylmethacrylate (PMMA), which requires the use of a catalyst for hardening of the cement. The catalyst, which is supplied in liquid form, must be mixed thoroughly with the methylmethacrylate monomer, and other dry components of the cement, to ensure a complete and even hardening of the cement. Preferably the cement is mixed under a vacuum to prevent air bubbles from being trapped in the cement. Air bubbles in the final cement mix may result in a cement with an undesirably low tensile strength. Typically, mixing of the cement components for between 0.5 to 2 minutes is required to obtain a cement mixture of the desired consistency.

Currently, devices available for mixing of bone cement require hand mixing. This procedure is very laborious and requires a sustained physical effort to complete the mixing process. If the mixing process is not adequate or if the cement hardens before it is delivered, the cement must be discarded and an additional batch prepared. If the process has to be repeated, the surgical procedure, which is under way by the time the cement mixing is commenced, is delayed.

The bone cement is, and should remain sterile, therefore, a "sterile" person is required to perform the mixing and handling of all the sterile components of the cement preparation. With bone cement mixers currently available, a "non-sterile" person is also required, in addition to the "sterile" person, to assist in the set-up of the cement mixing apparatus and for handling of all non-sterile components involved in the mixing procedure. At the end of the mixing procedure an additional "sterile" person is often required to assist in the transfer of the cement into cartridges for delivery of the bone cement to the patient. Therefore, preparation of the cement requires at least two and often as many as three people.

The components of the pre-cured cement, methylmethacrylate monomer and catalyst, are irritants and potentially toxic. Therefore, inhalation of the cement components,

1 particularly the monomer, is preferably avoided. Bone cement mixers currently available are
not sealed throughout the mixing process and require that the components be manually
dispensed into the bone cement mixer, thus exposing the operator to their fumes. These
fumes may then be inhaled, for an extended period of time, by all personnel in the vicinity
5 of the cement preparation, making cement preparation irritating and potentially hazardous to
their health.

After the cement is mixed, it is poured into a cartridge for dispensing to the site for
cementing. At this time, all instruments which have come in contact with the cement must
be thoroughly cleaned or discarded. An additional problem with transferring the cement is
10 the possibility of folding in air pockets that could negatively affect the cement/bone interface
and reduce the cement's bonding strength.

It is desirable that an apparatus be provided which requires only a single operator to
complete all the steps necessary to set-up the apparatus and to mix the cement. It is also
desirable that the apparatus isolates all the fumes associated with the cement preparation to
15 thus reduce exposure of hospital workers to these toxic compounds. It is also desirable that
such an apparatus be motor driven to avoid the physical endurance required to mix cement
and also to ensure reproducible mixing which reduces the need to dispose of cement batches
that are unacceptable. It is also desirable that all parts of the device which come in contact
with the cement are disposable so that clean-up is minimized.

20 Summary of the Invention

A motorized mixer for mixing bone cement for use in attachment of prosthetics and
method for using the mixer is described. The mixer comprises a mixing chamber, a liner
in the mixing chamber, an impeller within the liner, a motor for driving the impeller and
25 programmable means for regulating the operations of the motor.

In operation dry components of the bone cement are placed in the mixer and vials
containing catalyst for the bone cement are placed in vial cavities within the mixer. The
mixer is sealed and the vials are broken to release the catalyst into the dry components of the
bone cement. The mixer is then started. The mixer runs under the control of a
30 preprogrammed mixing sequence. At the end of the mixing sequence the mixed cement is
collected.

In a preferred embodiment of the present invention, the preprogrammed mixing
sequence comprises applying a vacuum to the interior of the mixer, starting a motor to drive
an impeller within the mixer, mixing for a preselected time period, re-applying a vacuum to
35 evacuate fumes from the interior of the mixer and applying pressure to the interior of the
mixer to discharge the cement from the mixer.

In another preferred embodiment of the present invention, the application of a vacuum
to the interior of the mixer is accompanied by the application of a vacuum to an attachable

1 bone cement gun cartridge or syringe through a hollow shaft of an impeller that exposes the
cartridge to the same vacuum as the mixing chamber. The impeller also seals off the
cartridge from the mixing chamber, preserving the cartridge's vacuum, when positive
pressure is introduced into the mixing chamber to aid in the transference of the bone cement
5 from the mixer to the cartridge. This configuration makes it easier to discharge cement to
the cartridge because no air pressure is in the cartridge to counteract the positive pressure
forcing the cement into the cartridge. It also helps prevent the introduction of air into the
cement during the discharge of cement from the mixer into the cartridge.

10 **Brief Description of the Drawings**

Features, aspects and advantages of the invention will be more fully understood when
considered with respect to the following detailed description, appended claims and
accompanying drawings where:

FIG. 1 is a perspective view of one embodiment of a bone cement mixer;

15 FIG. 2 is a perspective view of another embodiment of a bone cement mixer;

FIG. 3 is a top view of a one embodiment of a bone cement mixer liner;

FIG. 4 is a front sectional view of the bone cement mixer liner taken along the line
4-4 of FIG. 3;

20 FIG. 5 is a side sectional view of the bone cement mixer liner taken along the line 5-5
of FIG. 3;

FIG. 6 is a top view, partly in section, of another embodiment of a bone cement mixer
liner;

FIG. 7 is a front view of the bone cement mixer liner taken along the line 7-7 of FIG.
6;

25 FIG. 8 is a side view of the bone cement mixer liner taken along the line 8-8 of FIG.
6;

FIG. 9 is a front view of one embodiment of an impeller for use in the present
invention;

FIG. 10 is a top view of the impeller illustrated in FIG. 9;

30 FIG. 11 is a front view of another embodiment of an impeller for use in the present
invention in position for mixing;

FIG. 12 is a front view of a collapsible paddle and a plunger of FIG. 11 in position
for evacuation;

35 FIG. 13 is a side view of one embodiment of a port in the liner, shown in the closed
position;

FIG. 14 is a side view of the port of FIG. 13, shown in the open position;

FIG. 15 is a side view of another embodiment of a port in the liner, shown in the
closed position;

1 FIG. 16 is a side view of the port of FIG. 15, shown in the open position;
FIG. 17 is a side view of another embodiment of a port in the liner, shown in the
closed position;
FIG. 18 is a side view of the port of FIG. 17 in the open position;
5 FIG. 19 is a top view of one embodiment of an adapter for cement dispensing
cartridges;
FIG. 20 is a side view of the adapter taken along line 20-20 of FIG. 19;
FIG. 21 is a side view of another embodiment of an adapter for cement dispensing
cartridges;
10 FIG. 22 is a front view of the adapter for cement dispensing cartridges of FIG. 21;
FIG. 23 is a front elevation of a key pad;
FIG. 24 is a perspective view of another embodiment of an impeller for use in the
present invention;
FIG. 25 is a front view, partly in section, of the impeller illustrated in FIG. 24;
15 FIG. 26 is a front sectional view of a "one way" gas flow stopper located in the shaft
of the impeller illustrated in FIG. 24; and
FIG. 27 is a front sectional view of the bottom end of the impeller shaft of FIG. 24
contacting the bottom of a mixing chamber to which is attached a bone cement gun cartridge.

20 Detailed Description

The present invention relates to a bone cement mixer 10, one embodiment of which
is illustrated in FIG. 1. A second embodiment of a bone cement mixer 10 is illustrated in
FIG. 2 (the same numbers are used for similar parts throughout this description). The bone
cement mixer of the present invention has the advantage of being motorized and automated
25 to minimize or eliminate contact, by the operator and others in the surgery, with the
components of the cement and fumes generated by the components of the cement.

In general, the bone cement mixer of the present invention comprises a housing 12
which is non-disposable and houses other non-disposable parts of the mixer such as motors,
batteries, programmable memory mechanism and a vacuum-pressure pump (not shown). The
30 non-disposable components are sterilized by autoclaving for use. The non-disposable parts
of the mixer do not come in direct contact with the cement.

The components which come in contact with the cement are disposable and are
supplied as a cement mixing kit, which comprises a liner 30, which fits into the housing and
comprises the necessary mixing impeller 90 for mixing the cement. Other disposable
35 components of the kit include a cement injector gun or adapters into which the mixed cement
is collected at the end of the mixing procedure. The disposable components of the mixer are
supplied in kit form which are supplied as pre-sterilized. The individual components of the
bone cement mixer are described in detail below.

1 In operation, liner 30 (see FIGs. 3-8, described in detail below) is placed in the mixer
housing 12 and an injector gun or adapters (not shown) are placed on the cement outlet of
the mixer. Components of the cement, such as the powder which includes the
5 methylmethacrylate monomer are then placed in the liner. Vials containing catalyst, for the
hardening of the cement, are placed in vial cavities 32 located in the liner. The bone cement
mixer is then programmed for the desired mixing time. Lid 14 of the housing is then closed
to seal the components of the cement within the mixer. Closing the lid also results in
10 breaking of the vials thus releasing the catalyst into the other cement components (see below
for a detailed description). A vacuum is applied to the interior of the liner to prevent the
formation of air bubbles in the cement as it is mixed and also to remove fumes generated
from the components of the cement. A vacuum may also be applied to a cement gun or
various cartridges for dispensing the cement, positioned below the mixing chamber, to
15 prevent the formation of air bubbles in the cement while it is discharged from the mixing
chamber to the cement gun. After the bone cement mixer has been evacuated the mixer is
started.

At the end of the preselected mixing time, the mixer stops automatically and, in one
embodiment of the present invention, sounds an alarm to alert the operator. A vacuum is
again applied to the chamber to evacuate fumes which have built up during the mixing
20 procedure. When the mixing is completed, the vacuum is released and pressure is applied
to the chamber to evacuate the cement from the mixer by pushing the cement through a port
located at the bottom of the mixer into the cement gun or various cartridges for dispensing
the cement. Prior application of a vacuum to the cement gun will assist in evacuation of the
cement from the mixer because no positive air pressure in the cement gun will be present to
25 counteract the pressure being used to discharge the cement. The disposable portions of the
mixer, i.e., the liner, can then be removed from the mixer housing and discarded after use.
The components of the mixer and its operation are described in detail below.

The mixer housing 12 (FIGs. 1 and 2) comprises a pair of lids 14 which are attached
to a housing body by a hinge (not shown) or other suitable means of attachment. The lids
each house a motor (not shown) that supplies the power for mixing. Motors suitable for use
30 in the present invention are motors such as conventional gear motors, pancake motors or the
like. The motors are preferably reversible so that mixing can be performed by mixing in one
direction for a period of time and then in the opposite direction, if desired, to ensure
complete mixing of the cement. Motors suitable for use in the present invention are gear
motors such as those sold by Globe of Dothan, AL, Model number 407A6008-2, which is
35 a 12 V, 120 rpm, reversible motor. *motor*

In one embodiment of the present invention the motor is controlled by a current
sensing mechanism. When the current required to operate the mixing motor exceeds a preset
level, the device automatically terminates the mixing cycle, sounds an alarm and begins

1 evacuation the cement from the mixer. This mechanism, therefore, indirectly senses the viscosity of the cement to ensure the cement is evacuated before it becomes too viscous to flow from the mixer and also prevents over-mixing of the cement which would result in the cement hardening too quickly.

5 In a preferred embodiment, the motorized mixer of the present invention is programmable so that different cement consistencies and/or compositions can be mixed effectively. For example, cement for tibial/acetabulum replacement surgery is generally preferred at a thick or viscous consistency and mixing of the cement components for about two minutes generates a suitable cement for this application. Cement for femoral application
10 is generally preferred at a thinner or less viscous consistency than tibial/acetabulum cement, because it has to be placed within the femur. Mixing of the cement components for about one minute generates a suitable cement for this application. Moreover, some bone cements require a "stop period" during mixing so that the cement may "set up" properly. These mix requirements could be placed in the "permanent" memory of the mixer. Alternatively, a
15 "custom" mix program could also be programmed by the user. Suitable programmable memory mechanisms are well known in the art and suitable devices for use in the present invention are devices such as Model No. 8748 sold by NEC or other similar devices sold by other manufactures of programmable controllers. The programmable controllers are included within the housing. In another embodiment of the present invention the "program" is "hard
20 wired" rather than incorporated into a programmable memory mechanisms.

Located on the front of the mixer housing is a key pad 16 (see FIG. 23). The key pad may include a display which displays mixing time elapsed and the level of vacuum or pressure within the chamber. Also, buttons which allow for programming such functions as mixing, pausing the mixing, applying and releasing vacuum and selecting a program option
25 may be included. Additional buttons may be included which allow the selection of a preprogrammed or custom mix protocol and re-setting the mixer program. The key pad may also include LED's to indicate the phase of the mixing cycle the mixer is currently executing and segmental LED's may be included to indicate the mixing time elapsed and the vacuum level within the chamber. LED's suitable for use in the present invention are made by
30 Kingbrite or "mil-spec" high temperature resistant LED's made by Hewlett-Packard. Key pads suitable for use in the present invention include membrane key pads which have an overlay such as a multi-layer polycarbonate, such as those sold by 3M or a silicone rubber.

When a custom mix is chosen the program parameters may also be specified using the key pad. In one embodiment the key pad for custom mixing times includes a group of
35 switches which are identified as numbers 0-9 for specifying mixing times. Included in the group of switches are switches to enter the program. Also located on the key pad is an alarm to indicate that a mix procedure has been completed. Lights can also be included to indicate that power is being supplied to the mixer.

1 In one embodiment of the present invention power for the mixer is supplied by
batteries which are included within the housing. Batteries suitable for use in the present
invention are rechargeable nickel-cadmium batteries (12 V, 2.8 Amp). These batteries will
typically run the mixer for three mixing cycles prior to requiring recharging. In an
5 alternative embodiment of the present invention the mixer can be connected to A.C. power
by use of a D.C. transformer. Such transformers are well known in the art. When batteries
are used as a source of power, a "low battery" indicator light is also included on the key pad.

Also included within the housing is a vacuum-pressure pump for evacuating the
interior of the liner during mixing. Pumps suitable for use in the present invention include
10 diaphragm pumps such as those made by ASF Inc. of Narcross, GA, which draw about 70
cm of mercury in vacuum mode and generate 100 psi in pressure mode of operation, used
in combination with solenoid valves such as those sold by Humphrey Valve Co. of
Kalamazoo, MI and vacuum transducers, made by Omega of New York, NY, which provide
a sensing mechanism to control and maintain the desired pressure level. The solenoid valves
15 are chosen to operate in a range of about 0-76 cm of mercury in vacuum mode and up to 120
psi in pressure mode of operation.

To sterilize the mixer for use the housing is autoclaved. Since the housing includes
the vacuum-pressure pump, the program controller, batteries and motors within the housing,
which are not readily removable, the housing also includes shielding for these components
20 to prevent them from being exposed to the high temperatures experienced during autoclaving.
Suitable shielding is provided by encasing the heat sensitive components in protective "cans"
made of materials such as glass-filled FORTRON grade of polyphenylene sulfide, such as that
sold by Hoechst Celanese of Chatham, NJ (which is suitable for use at temperatures up to
about 280°C) EKTAR, a 15% glass-filled thermoplastic co-polymer resin sold by Eastman
25 Performance Plastics of Kingsport, TN (which is suitable for use at temperatures up to about
255°C) or ULTEM sold by General Electric.

On the underside of each lid 14 is a seal 17 which seals against the housing when the
lid is closed. Also located on the underside of each lid is a drive socket 18, which connects
30 the motor to a paddle or impeller shaft 92 of the liner. The end of the shaft has, in a
preferred embodiment, a pentagonal cross section to prevent slippage between the shaft and
drive socket. While a pentagonal shape is preferred, it is understood that other shapes such
as triangular, square and hexagonal would also be suitable.

Also located on the underside of the lid are blades 20, so that when the lid is closed,
the blades extend into vial cavities 32 of the liner to break and thereby open vials contained
35 in the vial cavities.

The housing body comprises a pair of chambers into which liners are placed (the
chambers are shown with the liners in place). Each of the chambers are open at their bottom
(not shown) to allow the liner to extend to the exterior of the housing and for the attachment

1 of cement collection adapters. O-rings are located around these opening to seal the liner in place.

5 The housing body is preferably mounted on a stand 22 projecting upward from a broad horizontal base 24 that provides support for the housing. The housing is preferably made from a high temperature plastic material such as ULTEM, made by General Electric, or VECTRA made by American Celanese Corp. However, areas that may come in contact with the cement, such as the area directly under the mixing chambers, are preferably made from, or coated with, a material such as stainless steel which can be easily cleaned to remove any cement that may be spilled during the preparation of the cement.

10 In one embodiment of the present invention (FIG. 1), a vacuum-pressure port 26 is also included in the lid. The vacuum port is connected to the vacuum pump, located in the housing of the mixer, by pressure resistant or vacuum tubing. The vacuum may also be connected to a "house" vacuum line as well as, or in place of, the vacuum pump. In another embodiment (FIG. 2), multiple vacuum-pressure holes 48 are located around the periphery of the liner. These holes communicate with a manifold in the liner that is connected to the vacuum pump and/or house vacuum line. In another embodiment vacuum/pressure holes 31 (FIG. 3) are provided in the liner at the ends of the vial cavities. In this embodiment the holes attach to a manifold in the housing, and communicate with the chamber of the liner via cavities placed in the lid (not shown).

20 Liner 30 of the present invention, illustrated in FIGs. 3-8, is made from materials such as polyethylene, and can be discarded after use.

25 In general, the liner comprises a cup shaped chamber 36 which forms a well of generally circular cross section, into which the components of the cement are placed for mixing. Located at the top of the liner, and at one or both sides, are vial cavities 32 into which are placed vials which contain the liquid catalyst for the cement. At the bottom of the liner is a port 130 for collecting the cement at the end of the mixing procedure. An impeller 90 is provided within the liner for mixing the cement.

30 In one embodiment of the present invention (see FIGs. 6-8) ribs 50 are placed along the outside of the liner and at its bottom that act to strengthen the liner and inhibit its collapse under the desired operating vacuum. In this embodiment of the present invention four ribs are placed around the outside of the liner and are equally spaced from each other. Matching grooves can be placed in the walls of the housing chambers, into which the liners are dropped, so that the ribs can act to align the liner within the housing. However, the ribs may result in stress risers with extended use or at high vacuum/pressure.

35 In one embodiment of the present invention the liner is evacuated via vacuum port 26 located in lid 14. In another embodiment (see FIGs. 6-8) a port 46 is located in the liner for connecting the liner to the vacuum-pressure pump. A series of holes 48 are located in the liner, in close proximity to the vacuum port connector and open to a manifold that is

1 connected to the vacuum port. These holes allow the interior of the liner to be evacuated and
vented as needed.

5 In another embodiment of the present invention (FIG. 27) the liner has an additional
hole 326 in the center of its bottom that is aligned with the bottom end of a hollow impeller
shaft 302 that fits snugly into the bottom of the liner. Liner hole 326 is aligned with hole
306 in the bottom of shaft 302 exposing conduit 320 to the interior of attached cement
cartridge 310 so that the air can be evacuated from the cartridge before the cement is
transferred after mixing.

10 Vial cavities 32 in one embodiment of the present invention (FIGs. 3-5) comprise a
shallow section 38 and a deep section 40 which are connected by an angled floor 42. In
operation, vials containing catalyst, are placed in the vial cavity in an horizontal position,
resting at one end on the floor of the shallow section and at the other end on a shelf 44 that
is at the same level as the floor of the shallow section and above the floor of the deep
section. A single vial is placed in one vial cavity when a single batch of cement is to be
15 mixed or, in those embodiments with two vial cavities per cup shaped chamber, a vial are
place in each of the two vial calvities when a double batch of cement is to be mixed. The
vial cavities are located in a position on the liner so that, when the lid of the mixer is closed,
the blades penetrate into the vial calvities, thus rupturing the neck of the vials in the vial
calvities. In the embodiments of FIGs. 3-5, the rupturing also results in the vial being
20 upended into the deep section of the vial cavity and ensures complete emptying of the
contents of the vial.

Catalyst is commercially available in different sized vials, which have different
lengths. Therefore, it is preferable that the vial cavity is able to accommodate the different
sized vials. In the case of the long vial, the vial cavity is of a dimension such that a long
25 vials will fit snugly into the vial cavity. When a shorter vial is used, the vial is held by the
close fit of the liner side walls 54 (FIGs. 3 and 6).

30 In another embodiment, a mechanism (see FIGs. 6-8) which comprises a plunger 56
is used to hold the small vial in place. The plunger extends along the length of the vial
cavity and through an end 57 to the exterior of the vial cavity. The plunger is attached to
a spring 58. When the vial cavity is empty, the plunger contacts the end wall 60 of the
cavity and the spring is relaxed. When the plunger is pulled away from the end of the vial
cavity, the spring is compressed and a small vial can be placed in the vial cavity. The
plunger, with the force applied by the spring, holds the vial in place and at the end of the
vial cavity. When a large vial is used, the plunger is drawn back along the full length of the
35 vial cavity, to allow the large vial to be placed in the vial cavity.

In another embodiment of the present invention (not shown), a tension spring is used
to hold the vial in the vial cavity. In this case a shorter plunger is attached to a tension
spring. The spring is attached to end wall 60 of the interior of the vial cavity. When the

1 plunger is drawn back to accommodate a vial, the spring is stretched and applies a force to the plunger which in turn secures the vial in place.

When the lid is shut, the vial is ruptured and the liquid contents of the vial are released and flow through a duct, into the liner chamber where they are mixed with the other
5 components of the cement.

In each embodiment of the present invention, the vial cavities are connected to the liner chamber by a duct 52. In a preferred embodiment of the present invention, a screen is located in the duct to prevent any glass slivers, that may result from the rupturing of the vial, from entering the cement mixture.

10 In the interior of the liner is a mixing impeller. In one embodiment of the present invention (see FIGs. 9 and 10) the impeller comprises two blades 94 extending from opposite sides of a shaft 96. The blades are bent at an angle of about 45° so that the extremities of the two blades are approximately parallel to each other (see FIG. 10). When viewed from the side (see FIG. 9) the blades form a roughly semicircular shape to conform to the shape
15 of the interior of the liner. In one embodiment of the present invention the blades include "cut-out" sections 98 which reduce the amount of blade which comes in contact with the cement thus reducing cement loss.

At the top end of the shaft is a cross-shaped member 100 which centers the shaft, and the blades, when the impeller is placed in the liner. In a preferred embodiment of the
20 present invention the top sides of the cross-shaped member are rounded to inhibit cement powder collecting on its tops when the cement powder is introduced into the liner. On the top of the shaft in the center of the cross-shaped member is shaft 92 which connects to the drive of the motor when the lid is closed. The end of the shaft comprises a generally pentagonal shaped projection for mating with the pentagonal shaped cavity of the socket.

25 In another embodiment of the present invention (see FIGs. 6-8), two pairs of arms 102 of an impeller bearing extend across the interior of the liner. Each of the arms is placed at 90° to each adjacent arm and is attached at one end to a centrally located cylindrical bearing 103. The arms are slanted downward to form a "V" shape. The outer ends, and the upper part of the "V", attach to the liner body. The powder components of the cement are
30 introduced into the liner by pouring them around the arms and into the well of the chamber of the liner. The downward slant of the arms prevents the powder from collecting on the arms.

At the intersection of the arms and extending upwardly through cylindrical bearing 103, in the center of the liner, is a shaft 96 which connects to the drive of the motor when
35 the lid is closed. The end of the shaft comprises a generally pentagonal shaped projection for mating with the pentagonal shaped cavity of the socket. It is desirable that the end of the shaft does not contain any cavity or other structure that could collect powder as the powder is introduced into the liner. When the lid is closed the shaft connects with the socket and

1 thus the drive of the motor. The matching pentagonal shapes of the shaft and the socket prevent the drive shaft slipping relative to the socket. Again, while a pentagonal shape is preferred, it is understood that other shapes such as triangular, square and hexagonal would also be suitable.

5 At a lower end of the mixer shaft 96 are paddles 94. When the mixer shaft is turned by the action of the motor the paddles move through the cement components thereby mixing them.

10 In another embodiment of the present invention (see FIGs. 24-27) two pairs of arms 301 of an impeller extend radially outward from opposite sides of the impeller shaft across the interior of the liner and then turn downward as shown in FIG. 24 eventually tapering to a narrower distance from the shaft at the bottom to fit the small end of the "bowl-like" liner. Each of the arms 301 then extend inward to reattach to shaft 302 at 180 degrees to each other. Vertical members 312 extend parallel to the impeller shaft on each side to extend between the upper and lower radially extended portions of the arms 301. These members help to stiffen the impeller blades. When viewed from the side, as shown in FIG. 25, the blades form a geometric pattern with minimal surface area to which cement can cling after mixing. In a preferred embodiment of the present invention, the top of the arms are rounded to prevent the powdered components of the cement from collecting on the thin top part of the blade arms when the cement is added to the liner.

20 Impeller shaft 302 has a hollow interior to form a central conduit 320 running from the top of the shaft to its bottom. At the top end of shaft 302 is a cross-shaped fitting 303 that attaches to the drive of the motor when the lid is closed enabling the attached motor to turn the impeller and mix the cement. The radial prongs 304 of the cross-shaped fitting 303 are open at the top and the ends exposing the interior conduit 320 to the interior of the mixer. The interior conduit has a wider diameter at its upper end 313 than at its lower end 314 (see FIG. 25). An inwardly extending lip 315 separates the wider diameter section from the lower diameter section.

30 Shaft hole 306 at the bottom end of shaft 302 (see FIG. 27) aligns with hole 326 in the bottom of the liner exposing it to the portable cartridge 310 (which in turn will be filled with mixed cement, removed from the mixer apparatus and attached to a bone cement gun). The outside diameter of bottom tip 325 of shaft 302 is less than the outside diameter of the rest of shaft 302 (see FIG. 27) and is hemispherical in shape. This allows the impeller shaft 302 to fit into a hemispherical depression or centering bearing at the bottom hole of the liner. The tight fit between the bottom tip 325 of impeller shaft 302 and the bottom of the liner (see FIG. 27) provides a sufficient seal to prevent the cement from leaking through prematurely.

35 At the top of shaft 302, positioned inside the interior conduit 320 and supported by lip 315, is a conventional "one-way" check valve 305 (see FIG. 26) that allows gas to flow up and out of conduit 320 into the mixing chamber, but prevents gas from flowing down

1 conduit 320. The "one-way" check valve 305 consists of a plunger 307 attached to spring
shaft 321 connecting to stopper 309. Ring 311 rests on edge 322 and spring lip 323. In its
closed position spring 308 pushes on plunger 307 which pulls stopper 309 down onto ring
5 plunger 307, the plunger causes spring 308 to contract and stopper 309 is lifted off ring 311
by spring shaft 321 allowing gas to pass through valve 305.

Applying a vacuum to the mixing chamber reduces the gas pressure in the mixing
chamber and the resultant greater gas pressure inside conduit 320 (exposed to cartridge 310)
pushes on plunger 307 overcoming the force of spring 308. This lifts stopper 309 off ring
10 311 exposing conduit 320 and cartridge 310 to a vacuum source which evacuates the gas
inside cartridge 310. Subsequently, as the gas pressure inside the conduit 320 and cartridge
310 approaches that of the mixing chamber, it is no longer sufficient to overcome the force
of spring 308. Spring 308 extends and causes stopper 309 to seal up against ring 311 and
the opening is closed. Likewise, when positive air pressure is introduced inside the mixing
15 chamber to help in the transfer of the cement to cartridge 310, stopper 309 is pushed down
against ring 311 and no air is allowed to flow down conduit 320. This preserves the vacuum
in cartridge 310. It is the combination of vacated cartridge 310 and the positive pressure in
the interior of the mixer that enhances delivery of the cement from the mixer into cartridge
310 after mixing is complete. Additionally, this reduces the likelihood that air pockets will
20 be folded into the cement during the transfer.

In another embodiment of the present invention (see FIGs. 11 and 12) a liner
comprises a paddle which is collapsible. The paddle 94 is of a fan-like construction. In this
design the collapsing of the blade is desirable since a plunger 104 is used to force the cement
out of the liner when the mixing procedure is complete. In this embodiment of the present
25 invention the plunger is moved to the bottom of the liner by the action of a spring 106. The
spring is coiled during the mixing procedure and is released when the mixing is completed.

It should be noted that at all times during the preparation of the cement, i.e., from the
time the lid is closed, the chamber of the mixer is sealed and fumes from the contents of the
chamber are unable to escape. Also, during the mixing procedure a vacuum is applied
30 which, on one hand prevents the formation of air bubbles in the cement and on the other
hand removes fumes from the chamber, preferably through the house vacuum line. Thus the
room in which the cement mixing procedure is performed remains relatively free of the
irritating and potentially toxic fumes which are normally associated with the preparation of
cement. It is only at the completion of the mixing procedure that the chamber is opened, at
35 its bottom, to allow the cement to flow from the chamber of the liner into a cartridge.

The vacuum applied to the interior of the liner during mixing is preferably about 55
cm of mercury. If a "stronger vacuum" is used the components of the cement may "boil"

1 or evaporate and the liner may implode. A "weaker vacuum" may be insufficient to "degas" the cement during mixing.

At the completion of the mixing procedure a vacuum is again drawn in the interior of the chamber to evacuate any fumes that have been generated during the mixing cycle. The vacuum is "released" and positive pressure is applied to the interior of the liner. The cement is then allowed to flow from the liner through a port at the bottom of the liner. As noted above, in one possible alternative embodiment, a plunger is used instead of or in addition to the positive air pressure to dispense the cement through the bottom port. The cement is collected into cartridges or syringes for dispensing the cement.

10 In yet another alternative embodiment, at the end of the mixing cycling when the impeller 300 with the hollow shaft is being used as shown in FIGs. 24-27, cartridge 310 attached to the bottom of the mixing apparatus will be vacated at the same time as the interior of the mixer. The hollow shaft 306 of impeller 300 is then sealed off from the interior of the mixer by valve 305 before the vacuum is "released", preserving the vacuum in the cartridge 310. This vacuum then aids in the transferring of "bubble free" cement from the mixer to the cartridge 310.

20 In one embodiment of the present invention, the port 130 (as illustrated in FIGs. 13 and 14) for removing the cement from the liner comprises a generally cylindrically shaped member 132. At one end of the cylinder is an aperture 134 comprised of multiple openings which mates with aperture 136 of the liner. In one embodiment of the present invention the cylindrically shaped member is attached to the liner by a "bayonet" type fit 139 (see FIGs. 13 and 14). In another embodiment the cylindrically shaped member is attached to the liner by welding.

25 The aperture 134 encloses an open grid. In the center of the grid is an attachment point 138, to which is attached a membrane 140, on the under side of the grid. When a vacuum is drawn in the chamber (see FIG. 13) the membrane is drawn flat against the aperture forming a seal. At the end of the mixing cycle, when pressure is applied to the chamber, the membrane is deflected away from the aperture allowing cement to flow out through the aperture (see FIG. 14).

30 At the opposite end of cylinder 132 is a second aperture 142. At the base of the second aperture is a attachment means which comprises two parallel slots 144 which run across the interior of the cylinder. The slots allow attachment of a detachable cement collection means 146 to be attached to the liner for collection of the cement after mixing. The collection means comprises flanges 149 which slide into slots 144. The collection means is held in place and sealed against the cylinder 132 by O-ring 147.

35 In another embodiment of the present invention, port 130 (see FIGs. 15 and 16) comprises a slide mechanism 153, and attachment means for the attachment of a cement collection device to the liner is similar to that described above. Flanges on the top of a

1 cartridge adapter slide into slots (as illustrated in FIGs. 13 and 14) attached to the bottom of
the mixer housing. As an adapter is pushed into place, it abuts lever 152 and slide 60 is
pushed away from a liner plug 154 located at the bottom of the mixer chamber, aligning
aperture 155 with the liner plug.

5 The port is in a closed position, as shown in FIG. 15, during the mixing procedure
and is held in the closed position by slide 153. During mixing the port retains the
components of the cement within the liner chamber. At the end of the mixing process, a
cartridge is slid into place, pushing the slide away from the plug, the vacuum is "released"
and positive pressure is applied to the liner chamber to thereby open the plug and force the
10 cement to flow into cartridges for dispensing.

15 In another embodiment of the present invention, illustrated in FIGs. 17 and 18, the
bottom of the mixer comprises a slot which is offset, by walls 157, from the main body of
the mixer housing. The slot is similar to that described above. In this design the liner,
which fits into the mixing chamber, has a bell shaped port 156 at its bottom end. At the top
of the port is a plug 158 which is contiguous with the floor of the liner, when in the closed
position. In the closed position the components of the cement are retained in the liner and
there is no "dead space" into which powder or liquid components could become trapped and
thereby, not mixed. The plug is held in place by the vacuum which is applied during the
mixing process and by a "crush rib" 160 on a hinge 162 which attaches the plug to the liner.
20 If the alternative embodiment in which the hollow shaft 306 of impeller 300, as shown in
FIGs. 24-26, is used to vacate cartridge 310 attached to the bottom side of the mixer, the
plug on the bottom side of the mixer will be held in place solely by a "crush rib" 160 on a
hinge 162 attached to the plug of the liner.

25 When the mixing of the cement is complete the vacuum is released and positive
pressure is applied to the inside of the liner. This positive pressure forces the plug out of
the liner and allows the cement to flow from the liner and into cartridges attached to the
bottom of the mixer. The cement is collected in the cartridges which can then be fit into a
cement injection gun for dispensing as required.

30 Dispensing of the cement is performed by placing the cement into a cartridge that fits
onto a cement injection gun, such guns are well known in the art. The cement injection gun
is then used to deliver the cement to the surgical site as required. Many different designs
of cement injection guns, and cartridges designed to fit them, are available. The cartridge
designs differ depending on the manufacturer of the cartridge and the use for which the
cartridge was designed. Some cartridges have screw tops while others have handles and
flanged tops and many of the available cartridges have different diameters. Some cartridges
35 have long nozzles, such as those designed to deliver cement to the femur, while others have
relatively short nozzles. In one embodiment of the present invention, an adapter 190, which

1 will fit all, or most of the available cartridge designs, is used to attach the cartridge to the mixer.

5 In one embodiment of the present invention, shown in FIGs. 19 and 20, cartridge holder or adapter 190 comprises a handle 194 attached at a top end to a top brace 196. The top brace comprises a central bore 198 through which the cement can flow from the mixer into a cartridge held in place by the adapter. The central bore is formed by a tube. On an upper side of the outer diameter of the tube are attached flanges 192 which attach the cartridge adapter to the mixer by sliding into slots 210 (illustrated in FIGs. 21 and 22) on the bottom of the mixer housing. The outer surface of the tube is stepped 200 to form
10 different sized diameters. Each of the different diameters is chosen to fit an internal diameter of a tubular cartridge. Thus the cartridge is attached to the top brace by pushing the cartridge over the appropriately sized diameter step thus forming a friction fit which holds the cartridge in place. The step also centers the cartridge below the bore so that cement can be delivered into the cartridge.

15 A bottom brace 202 comprises a ring 204, the internal diameter of which is stepped 205 to accommodate the outside diameter of the various tubular cartridges that are commercially available. A central bore 206 in the ring allows different types of cartridges, such as those with long nozzles, to be fitted into the bottom brace. A thimble shaped member 207 is attached to the outer perimeter of the ring. The ring is attached to the handle by forcing the thimble shaped member over a projection 208 attached to the base of the handle. When the bottom brace is attached to the handle, a cartridge is held securely in place.

25 In another embodiment, an adapter is designed for use with cartridges which have flanges at the top of their tubular structure as shown in FIGs. 21 and 22. Adapters for use with such cartridges comprise a flange capture member 210 or slot which is the same as that described above. Generally commercially available cartridges which have a flanged top 192 are relatively small and in use it is desirable to have two such cartridges filled with cement at the same time. Therefore, it is desirable that the cartridge adapter have places for two cartridges.

30 In this embodiment of the present invention, the adapter handle 214 is attached to a holder which comprises two slots 216 on its lower side, adjacent to each other, into which are slid the flanges 212 of the cartridges 218. At a top side of the adapter are flanges for attaching to the bottom of the mixer, as described above. The adapter preferably comprises a means for diverting the cement, as it flows from the mixer, to each of the cartridges. The adapter comprises a lever 220 attached to a handle 222. When one cartridge is being filled the lever is in a first position which allows the cement to flow into a first cartridge. When the first cartridge is full the handle is moved so that the lever allows the cement to flow into a second cartridge.

1 In another embodiment the adapter of FIGs. 20 and 21 may include an "angled" top
brace so that, when installed on the mixer, the adapter is angled away from the perpendicular
plane to allow for clearance of large adapters and to allow easy fitting and removal of the
adapters.

5 In operation, the housing 12 is sterilized by autoclaving and then connected to house
vacuum line in the operating room. A presterilized bone cement kit is opened and liner 30
is placed in the mixer housing 12 and an injector gun or adapters (not shown) are placed on
the cement outlet of the liner. Components of the cement, such as the powder which
includes the methylmethacrylate monomer are then placed in the liner and vials containing
10 catalyst, for the hardening of the cement, are placed in vial cavities 32 located in the liner.
A programmed specifying the desired mixing and holding times, sequence of vacuum pump
and mixer operation or other desired parameters are input via the key pad. Lid 14 of the
housing is then closed to seal the components of the cement within the mixer.

15 Closing the lid breaks the vials, releases the catalyst into the other cement components
and initiated the preprogrammed functions. A vacuum is applied to the interior of the liner
to prevent the formation of air bubbles in the cement as it is mixed and also to remove fumes
generated from the components of the cement. After the bone cement mixer has been
evacuated the mixer is started.

20 At the end of the preselected mixing time, the mixer stops automatically and, in one
embodiment of the present invention, sounds an alarm to alert the operator. A vacuum is
again applied to the chamber to evacuate fumes which have built up during the mixing
procedure. When the mixing is completed, the vacuum is released and pressure is applied
to the chamber to evacuate the cement from the mixer by pushing the cement through a port
located at the bottom of the mixer into a cement gun or various cartridges for dispensing the
25 cement.

In a preferred embodiment of the present invention, the liner, alone or along with the
cartridge adapter, are supplied in pre-sterilized packets. Therefore, the packets only need
to be aseptically opened and the liners placed in the mixer chamber, for the bone cement
mixer to be ready for use. Such procedures can easily be performed by a "sterile" person
30 and an additional "non-sterile" person is not required for the routine operation of the mixer.

At the end of the mixing procedure the cartridge adapter packet is opened and a sterile
cartridge is placed in the adapter, which is then attached to the mixer. The cement then
flows into the cartridge without any intervention by the operator. Again this procedure is
easily performed by a "sterile" person without the assistance of a "non-sterile" or an
35 additional "sterile" person. Therefore, the operation of the mixer is easily carried out by a
single person, reducing the need for additional staff in the cement mixing procedure.

The above descriptions of exemplary embodiments of a mixing apparatus are for
illustrative purposes. Variations will be apparent to those skilled in the art. For example,

1 an injection gun designed specifically for use with the bone cement mixer could be used in
place of the cartridge adapters described. Therefore, the present invention is not intended
to be limited to the particular embodiments described above. The present invention may also
5 be practiced in the absence of any element not specifically disclosed. The scope of the
invention is defined by the following claims.

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1 **WHAT IS CLAIMED IS:**

1. A motorized mixer for mixing bone cement for use in attachment of prosthetics,
the mixer comprising:

5 a mixing chamber;

 a liner in the mixing chamber;

 an impeller within the liner wherein the impeller comprises:

 blades for mixing;

 a hollow shaft;

10 a motor for driving the impeller; and

 means for regulating the operations of the motor.

2. A motorized mixer as recited in claim 1 that further comprises an impeller with
a first open end exposing the mixing chamber to the interior of the shaft.

3. A motorized mixer as recited in claim 1 that further comprises an impeller with
a second open end that protrudes through the liner and mixing chamber into the post-mixing
cement collection area.

4. A motorized mixer as recited in claim 3 where the second open end exposes the
interior of the shaft to the post-mixing cement collection area.

5. A motorized mixer as recited in claim 1 that further comprises a hollow
impeller with a "one way" gas flow valve that allows air to pass up and out of the shaft and
post-mixing cement collection area, but doesn't permit air to flow down the shaft from the
interior of the mixing chamber;

6. A method for preparing bone cement comprising the steps of:
 placing components of the bone cement in a mixer;
 sealing the components of the cement within the mixer;
 attaching a cement collection device to the bottom of the mixer where the
attachment is air tight;
 applying a vacuum to the interior of the mixer;
 mixing the cement components under a vacuum for a selected time period; and
 applying a vacuum to the cement collection device before the mixed cement is
transferred from the mixer to the cement collection device.

1 7. A method of preparing bone cement as recited in claim 6 wherein the application of a vacuum to the interior of the mixer and the cement collection device occurs simultaneously.

5 8. In an impeller used in a mixer for mixing bone cement having a mixing chamber, a liner in the mixing chamber, and a means for mixing cement within the chamber wherein the improvement comprises a hollow shaft with an interior, the hollow shaft having a first open end exposing the mixing chamber to the interior of the hollow shaft, the hollow shaft having a second open end aligned with a liner opening in the liner, and the second opening and the liner opening exposing the interior of the hollow shaft to a post-mixing cement collection area so that air in the mixing chamber is exposed to air in the post-mixing cement collection area.

15 9. In an impeller used in a mixer for mixing bone cement having a mixing chamber and means for mixing cement within the chamber wherein the improvement comprises a hollow shaft having an interior, the hollow shaft having a first open end exposing the mixing chamber to the interior of the hollow shaft, and the hollow shaft having a second open end exposing the interior of the shaft to a post-mixing cement collection area.

20 10. In an impeller as recited in claim 9 wherein the hollow shaft contains a "one way" gas flow valve that allows air to pass up and out of the hollow shaft and the post-mixing cement collection area, but does not permit air to flow down the hollow shaft from the mixing chamber.

25 11. In an impeller as recited in claim 9 wherein the mixer has a motor and a battery power source for driving the motor.

30 12. In an impeller as recited in claim 11 wherein the battery power source comprises a rechargeable battery source.

 13. In an impeller as recited in claim 11 wherein the battery power source comprises a nickel-cadmium rechargeable battery source.

35 14. In an impeller as recited in claim 9 wherein the mixer has a DC motor adapted to be powered by an AC power source through a DC converter.

 15. The mixer according to claim 1 further comprising a battery power source for driving the motor.

1 16. The mixer according to claim 15 wherein the battery power source for driving
the motor comprises a rechargeable battery.

5 17. The mixer according to claim 15 wherein the battery power source for driving
the motor comprises a nickel-cadmium rechargeable battery.

10 18. The mixer according to claim 1 wherein the motor is a DC motor and further
comprising a DC converter to convert AC current to DC current to power the motor.

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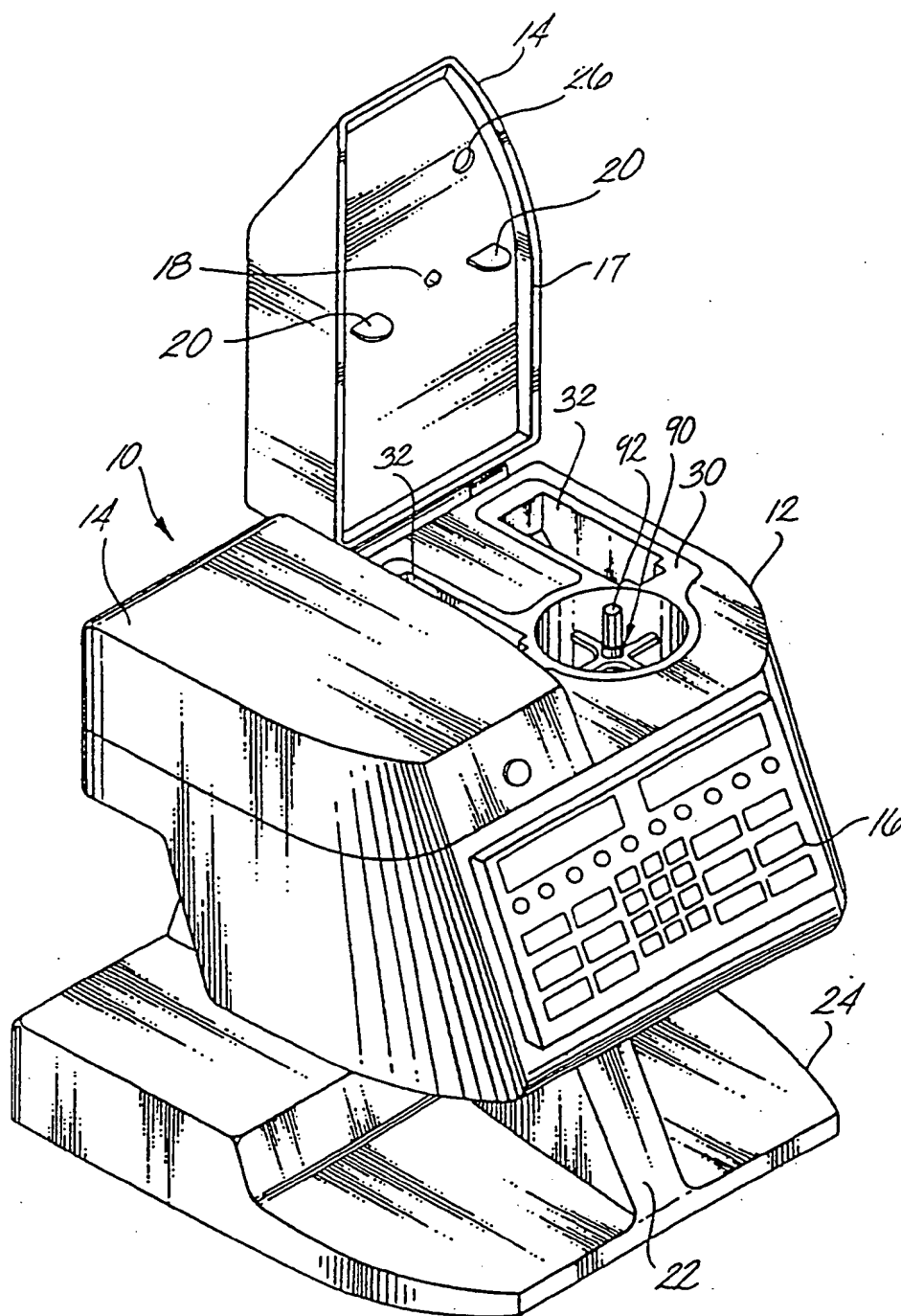
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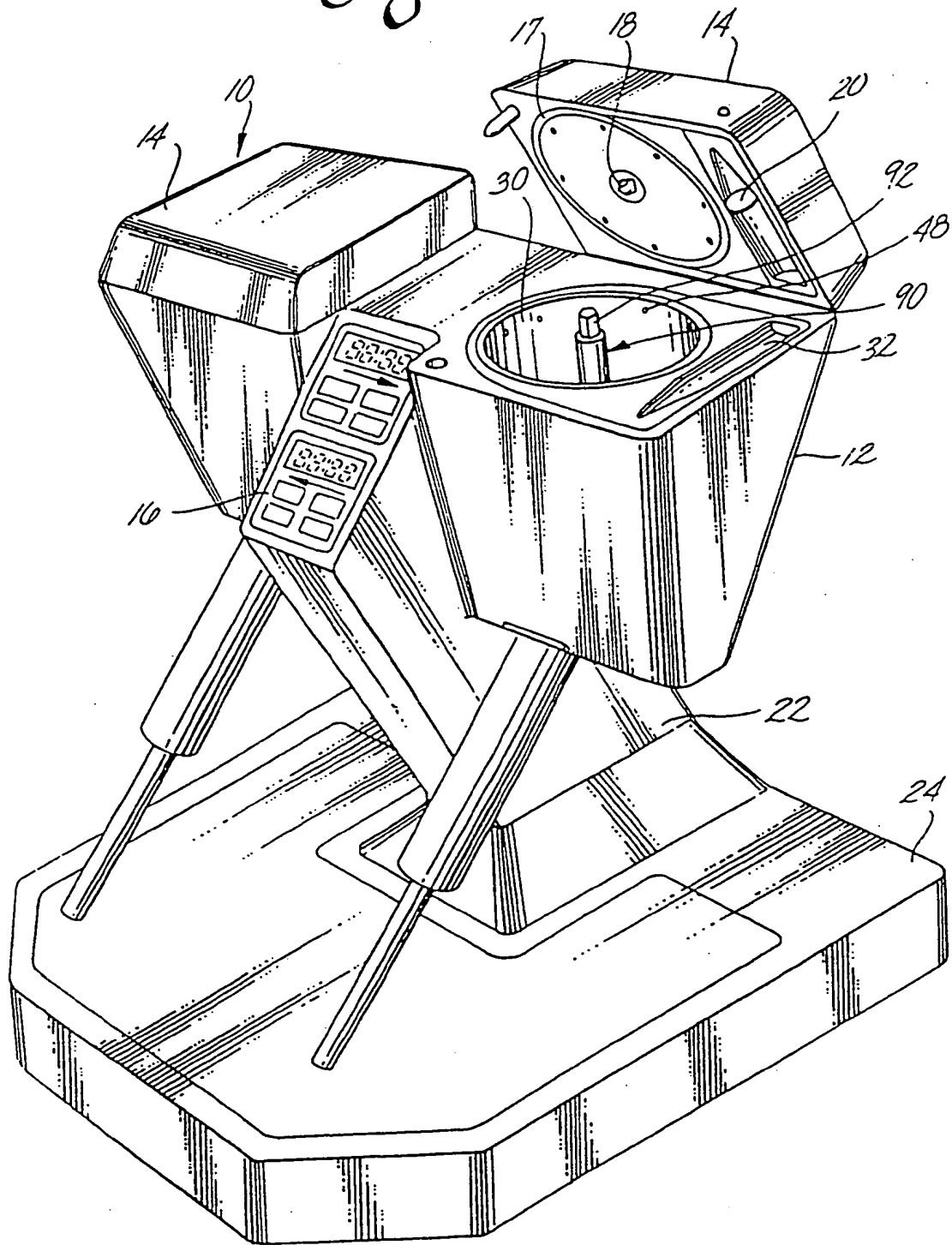
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Fig. 1

2/16

Fig. 2

3/16

Fig. 3

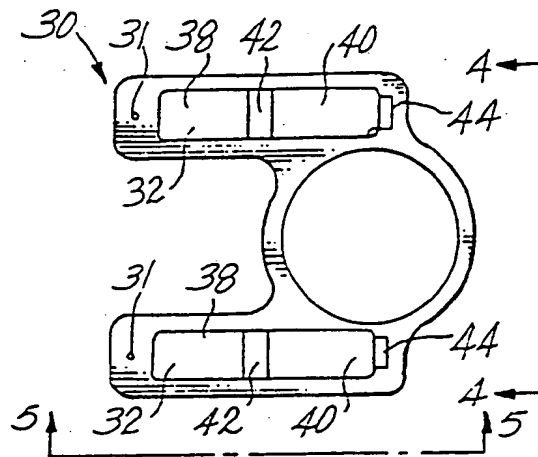


Fig. 4

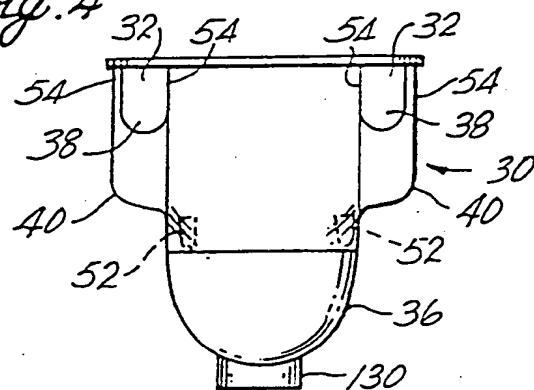
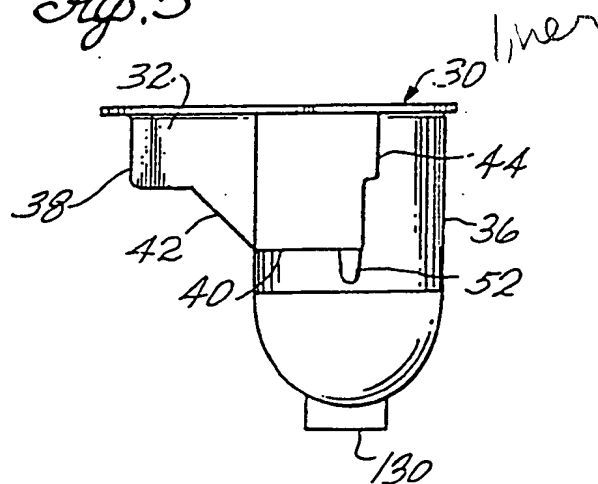


Fig. 5



4/16

Fig. 6

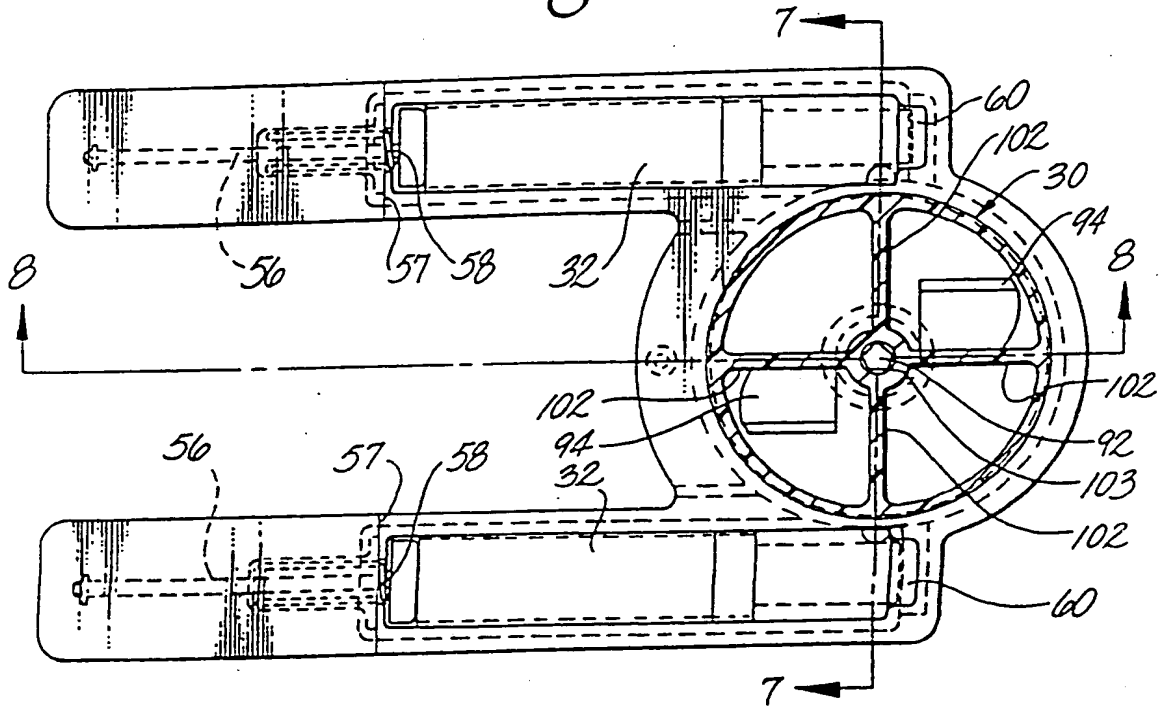


Fig. 8

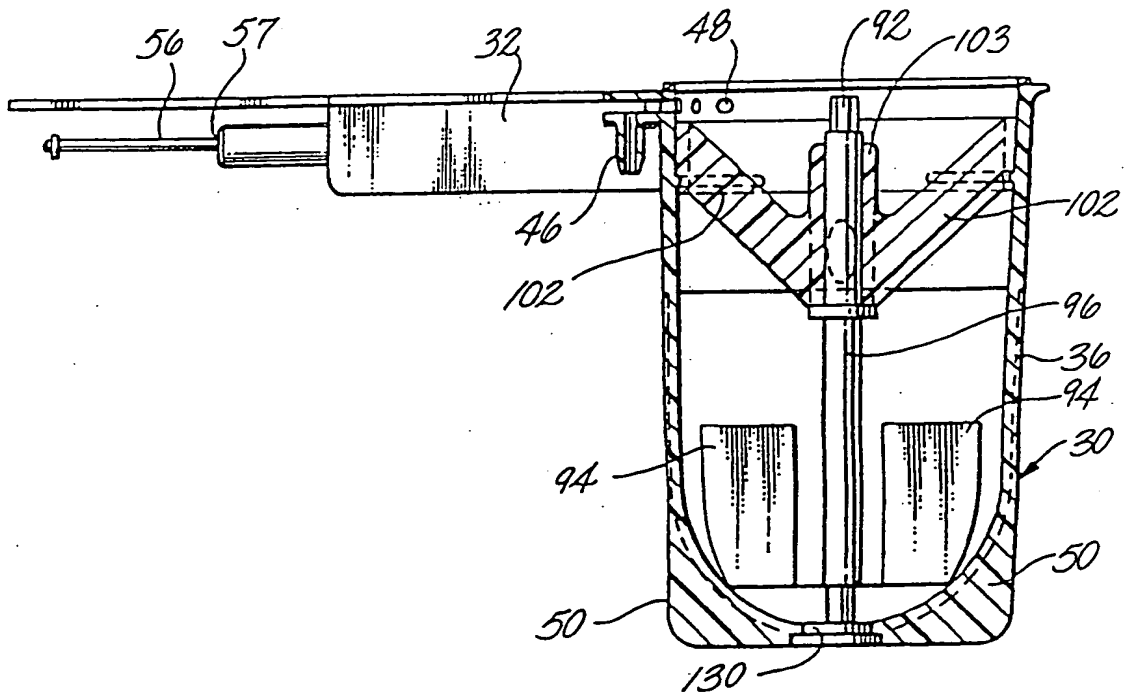
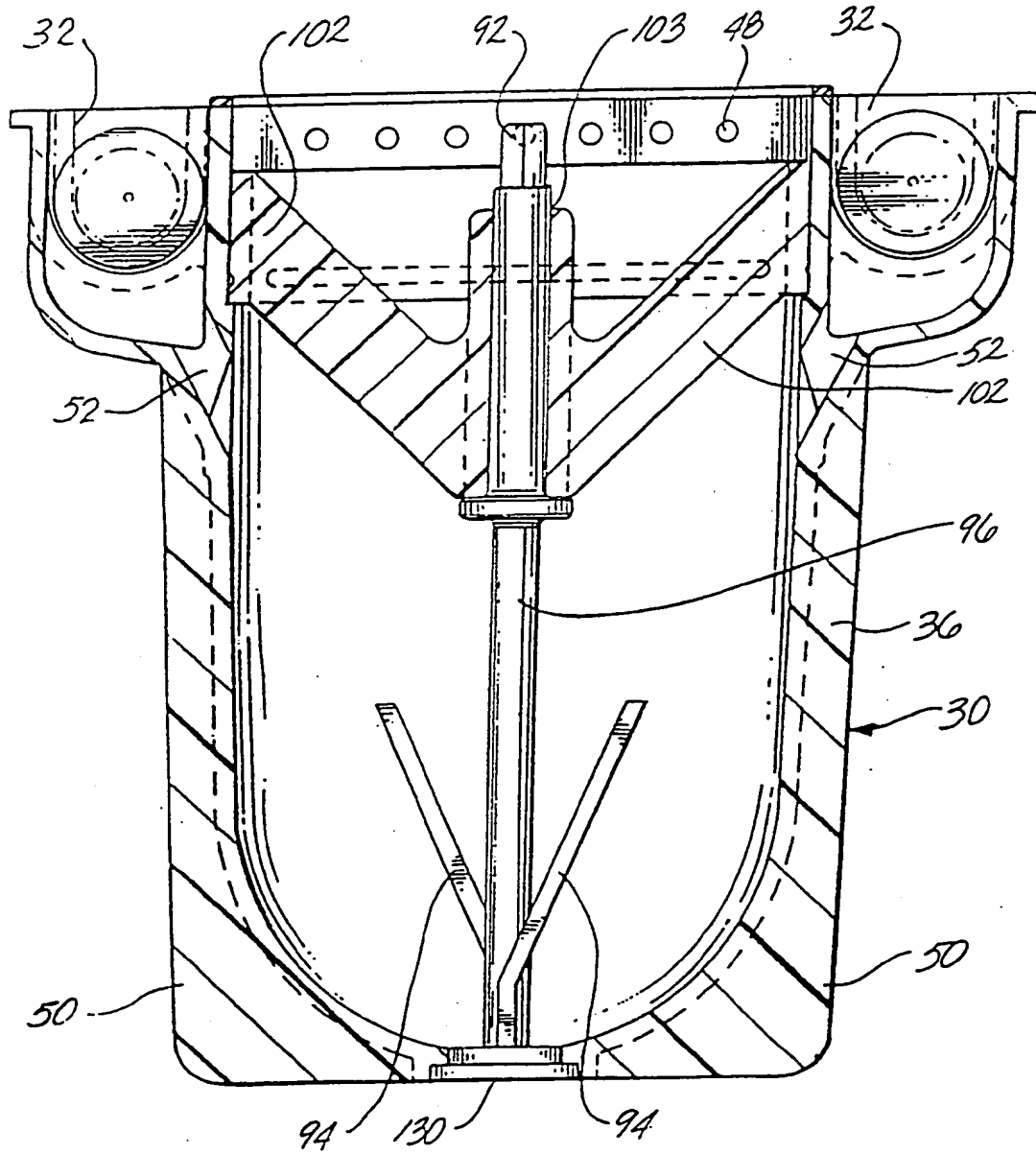
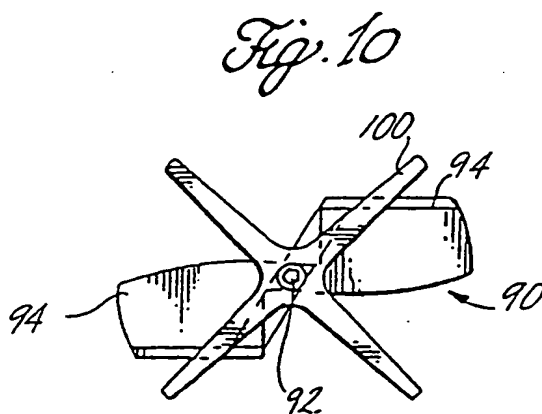
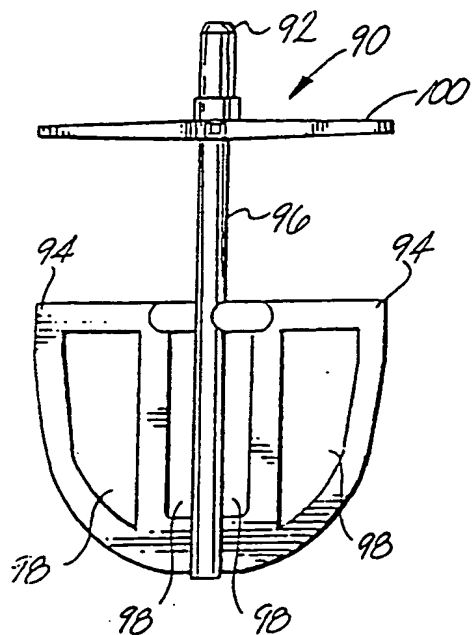


Fig. 7



7/16

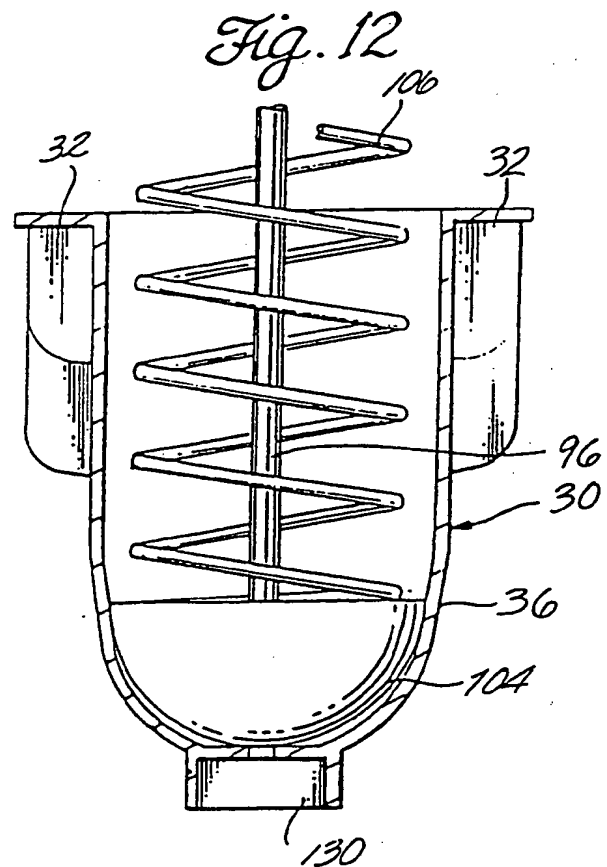
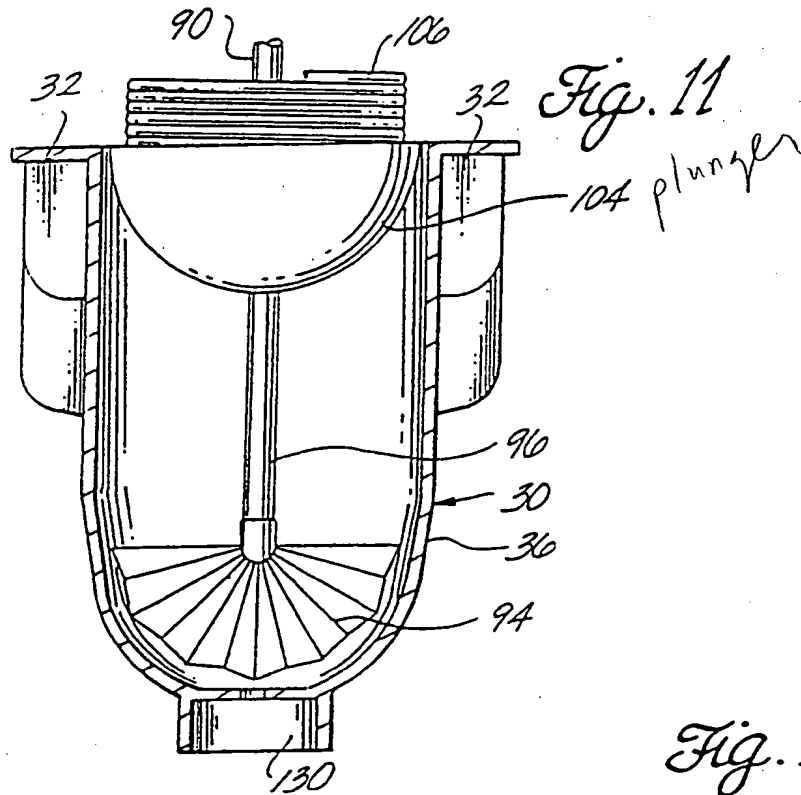


Fig. 13

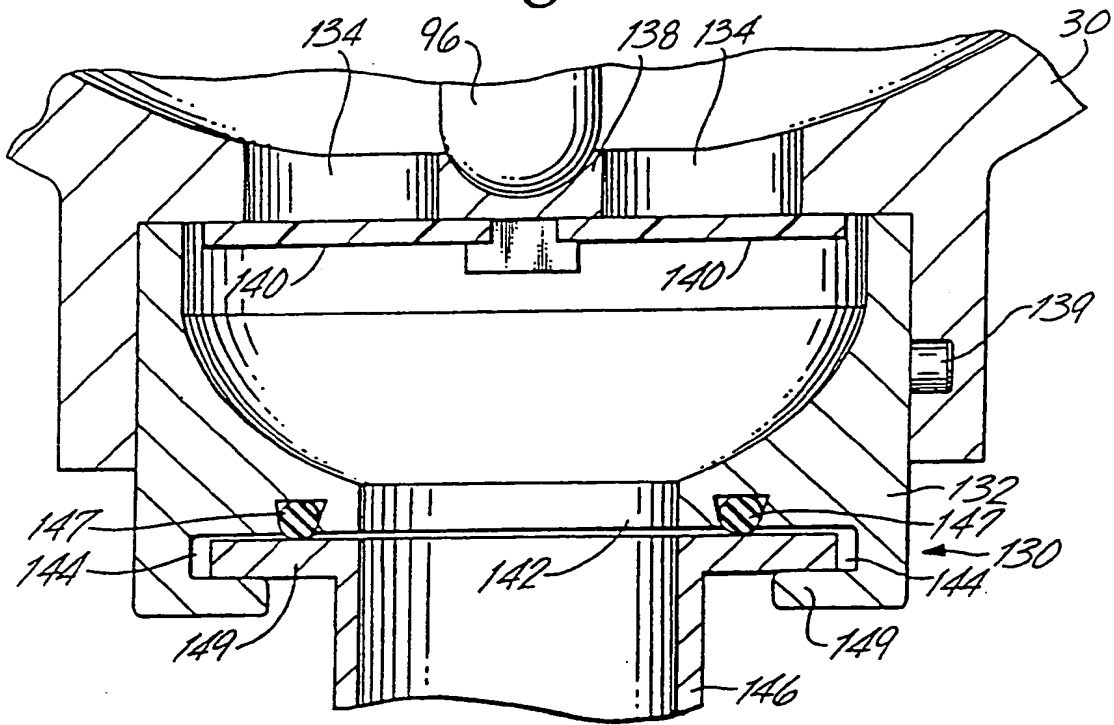
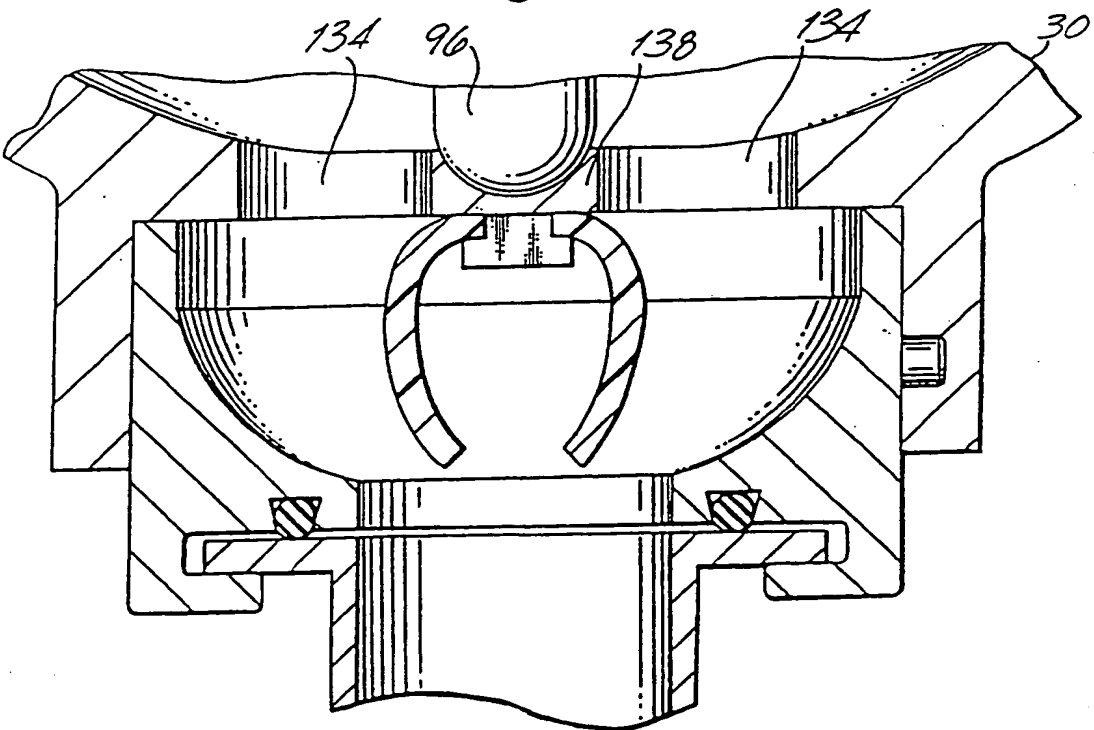
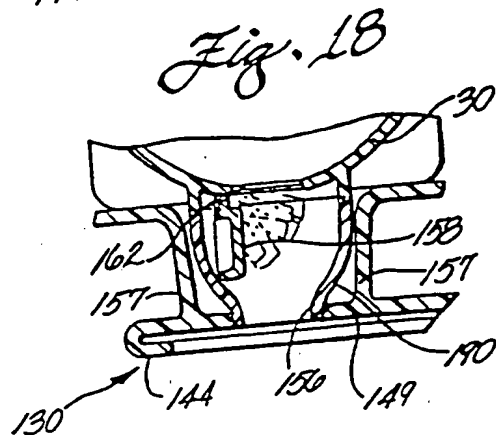
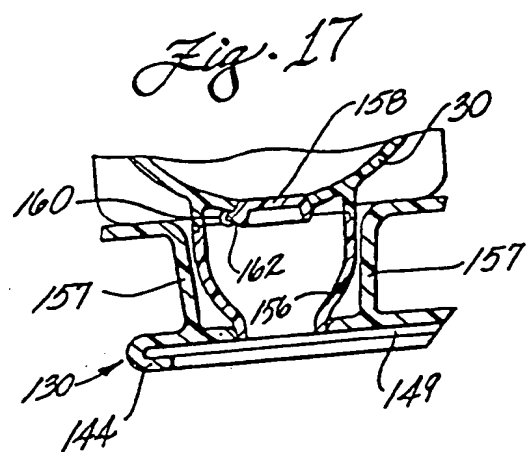
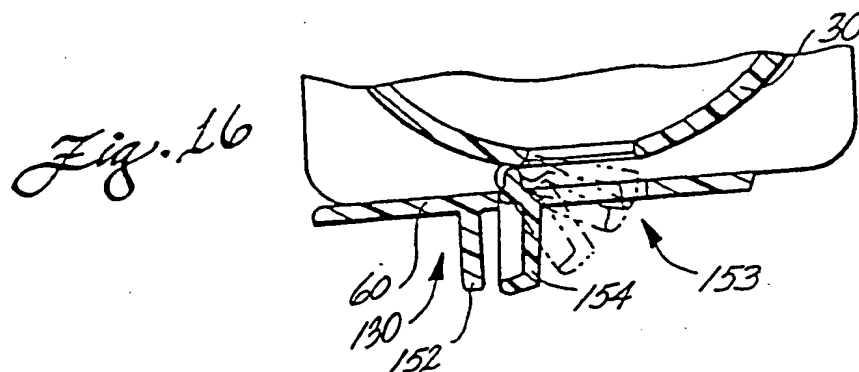
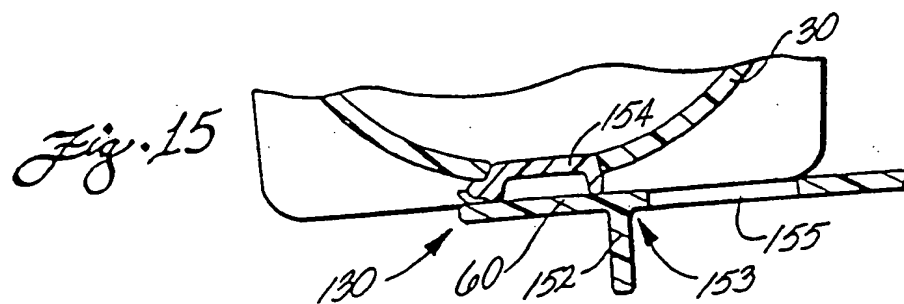


Fig. 14



9/16



10/16

Fig. 19

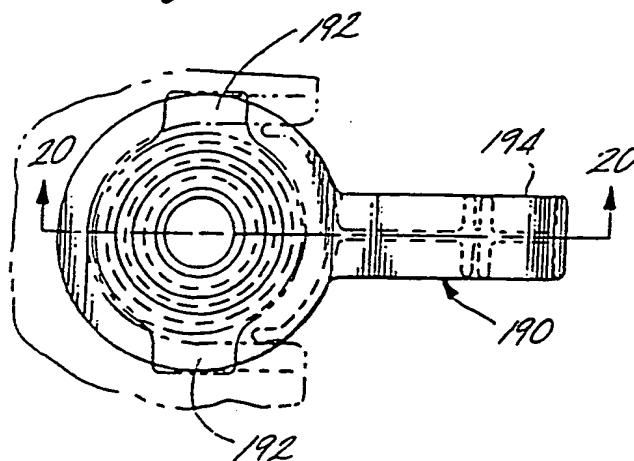
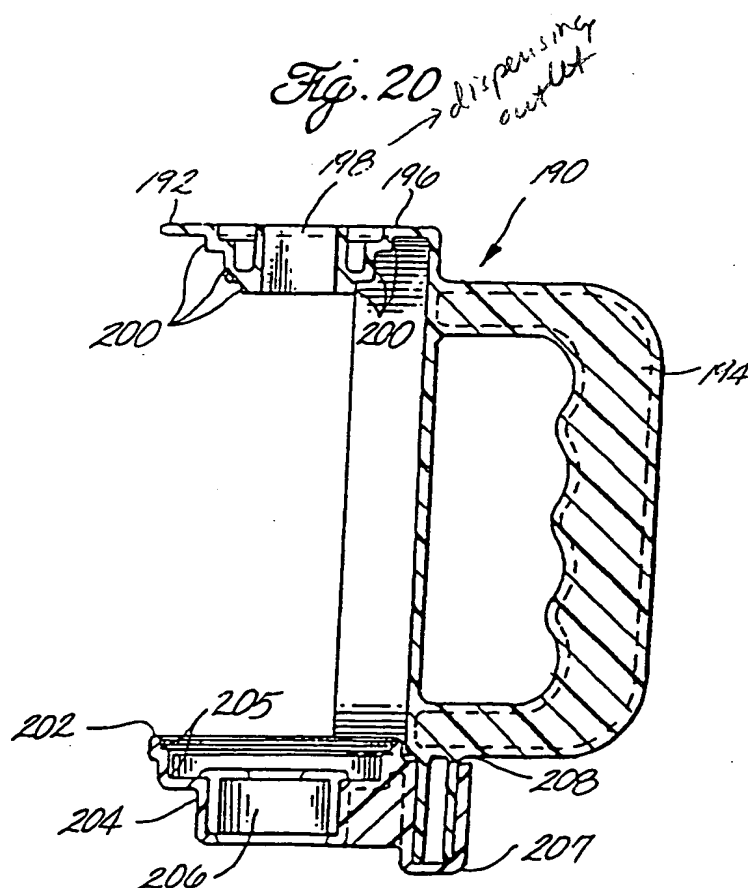
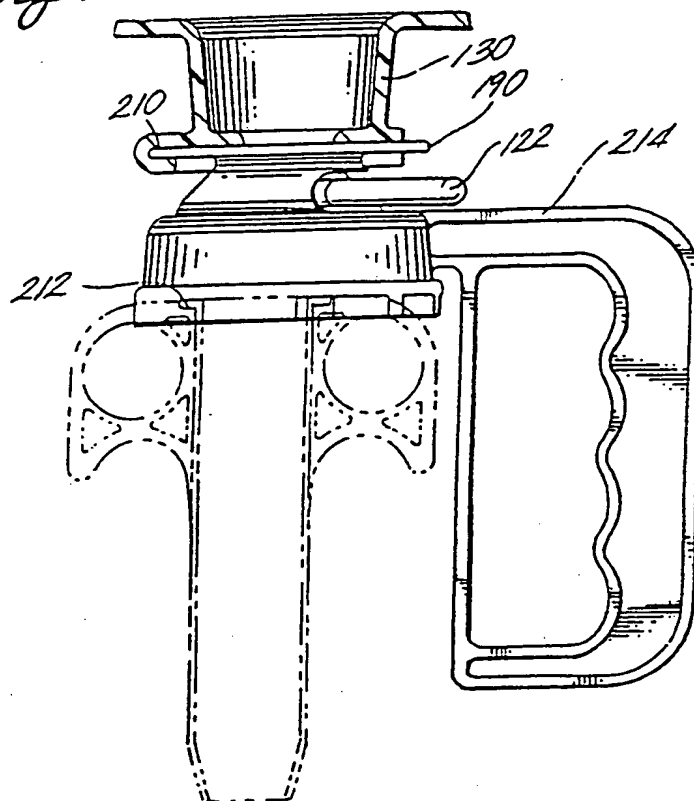
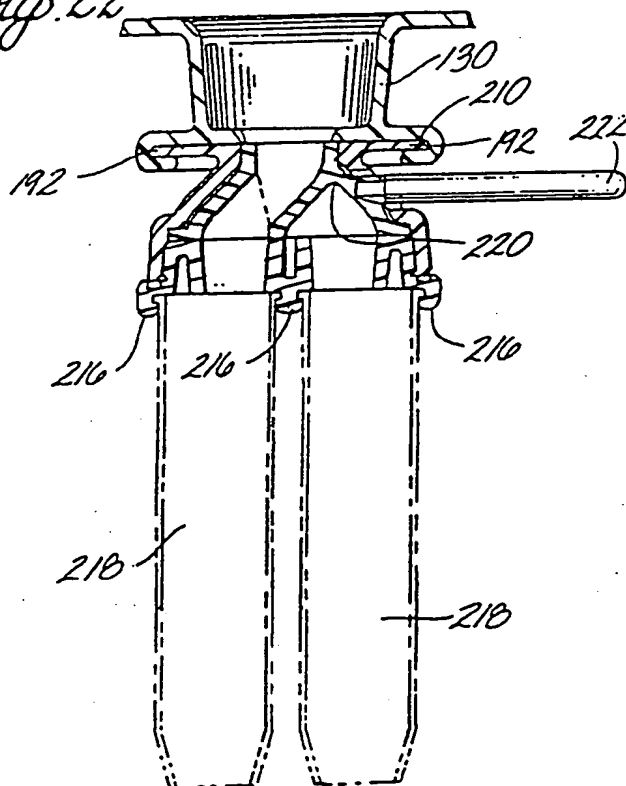


Fig. 20



11/16

Fig. 21*Fig. 22*

12/16

Fig. 23

MIXER #1

MIN. ☐

PAUSE ☐

SEC. ☐

MIX ☐

HG" ☐

EVAC ☐

MALFUNCTION ☐

PROG ☐

PAUSE ☐

VAC ☐

☐ MIX PAUSE

☐ CUSTOM MIX

☐ SINGLE DOUBLE

☐ TIBIAL ACETAB

☐ HUMERAL FEMORAL

☐ CANCEL

MIXER #2

LO BATT ☐

MIX ☐

EVAC ☐

PROG ☐

☐ MIX PAUSE

☐ CUSTOM MIX

☐ SINGLE DOUBLE

☐ TIBIAL ACETAB

☐ HUMERAL FEMORAL

☐ CANCEL

1

4

7

PROG

2

5

8

0

3

6

9

ENTER

ORTHOMIX

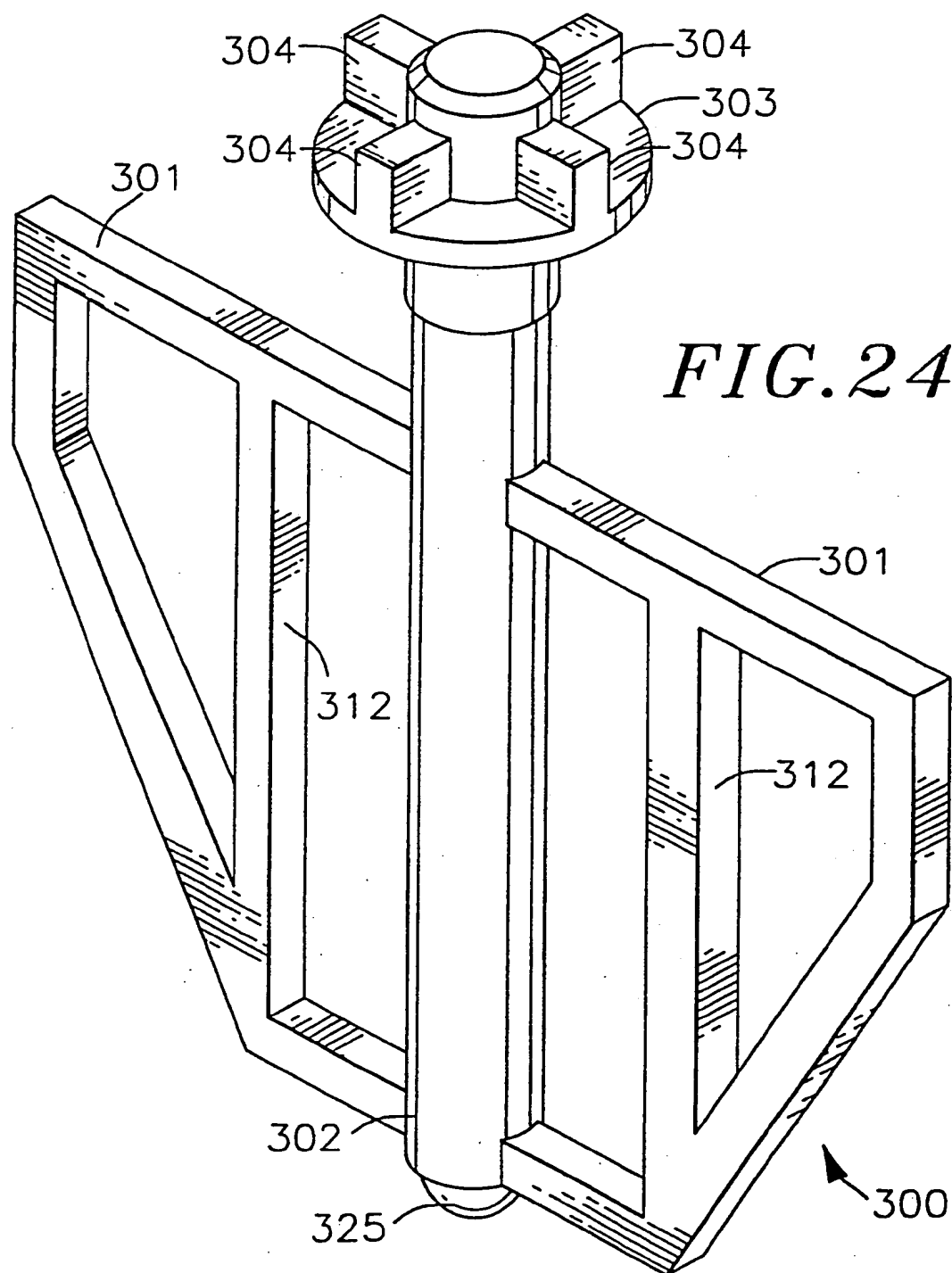


FIG. 25

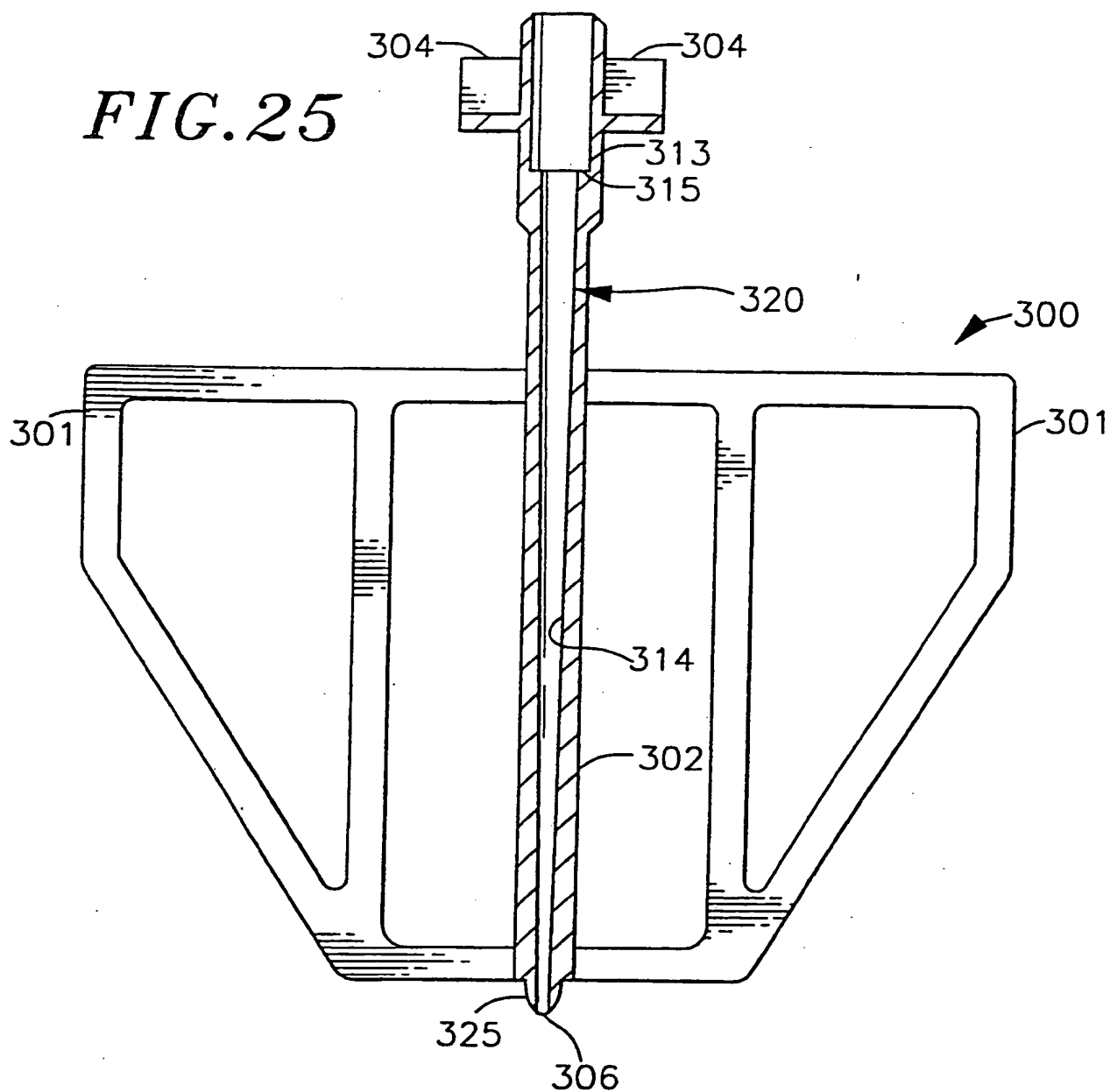


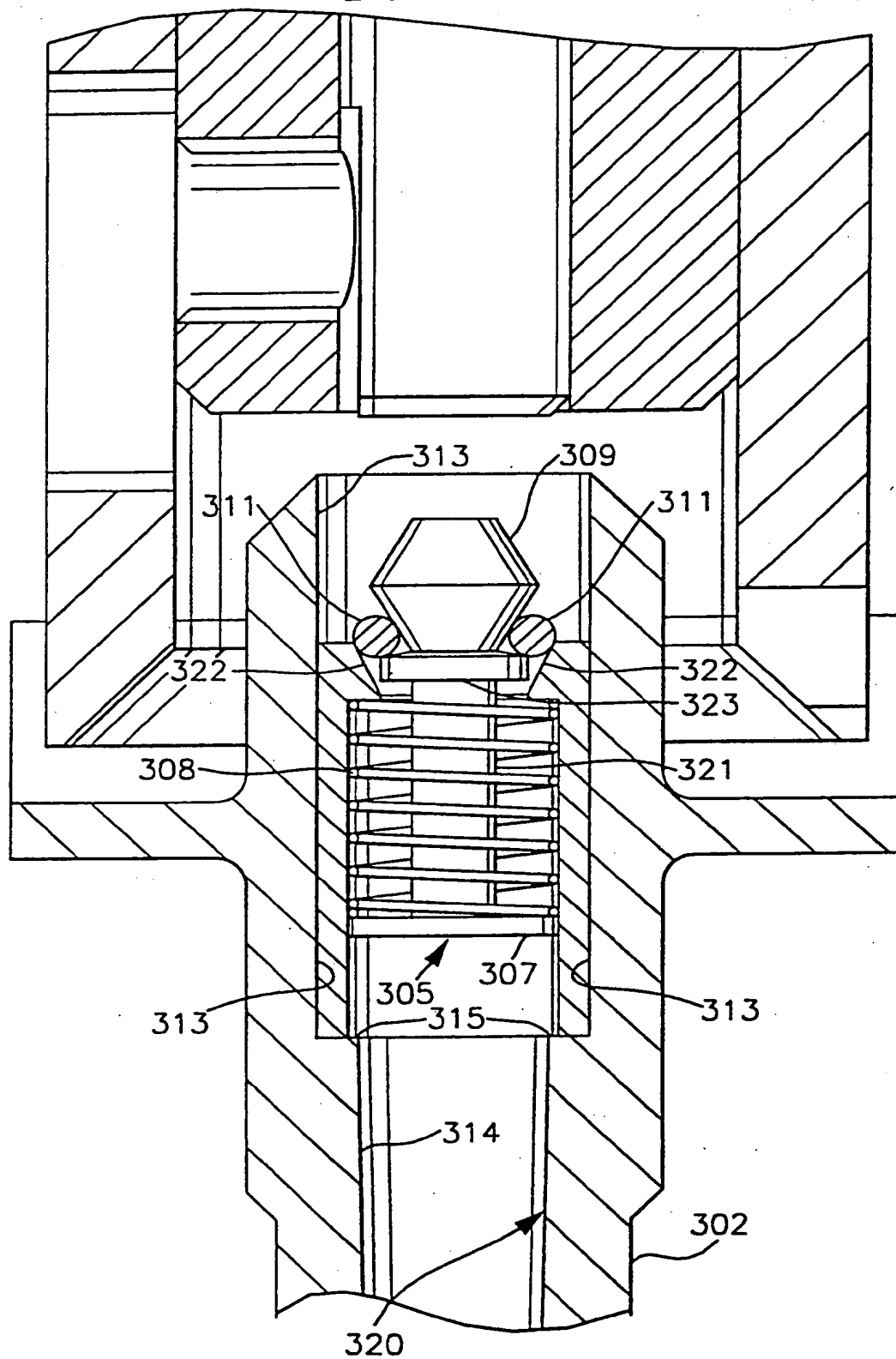
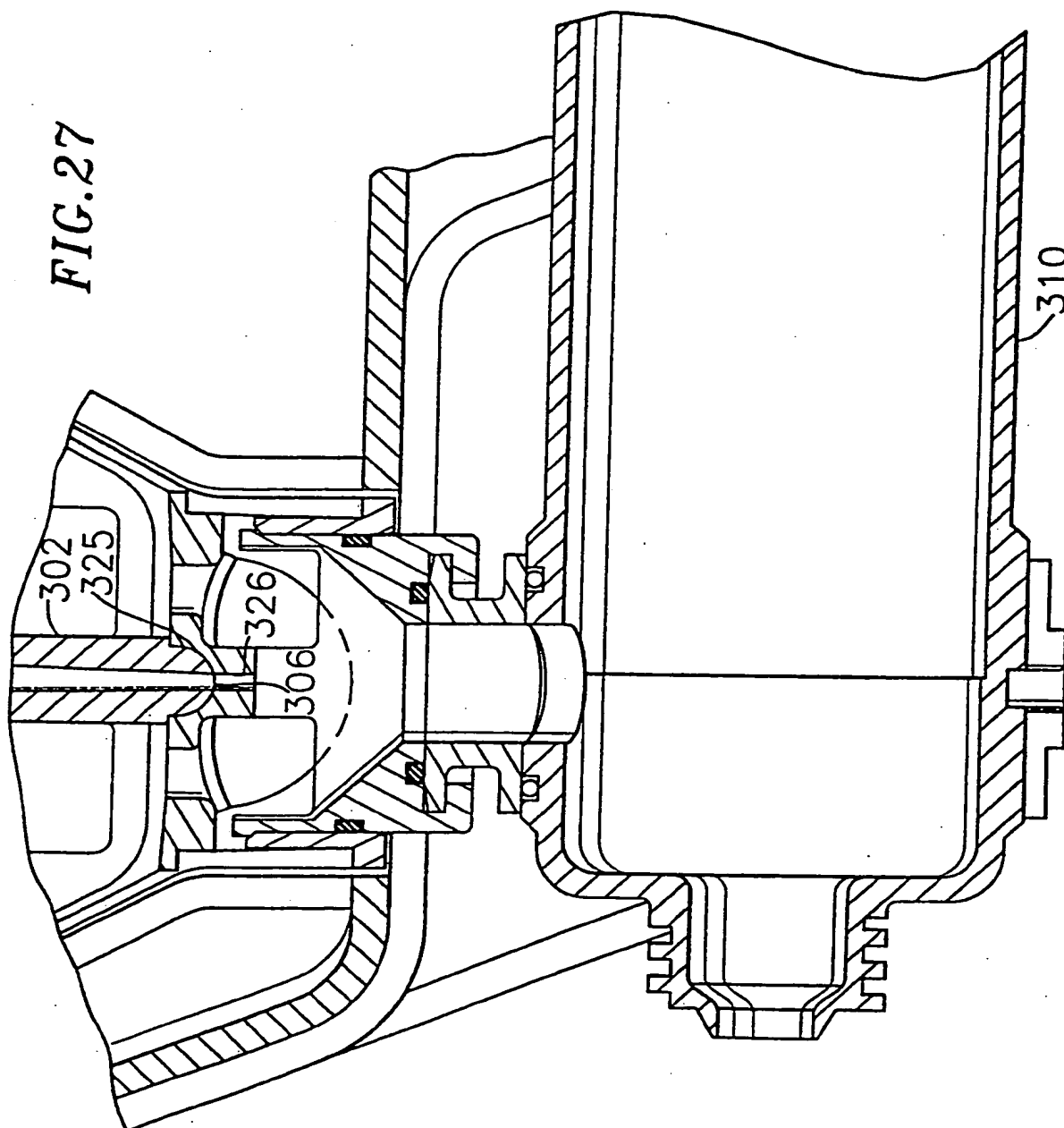
FIG. 26

FIG. 27



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/09611

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :B01F 13/06

US CL :366/139, 279, 184

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 99/348, 472; 366/75, 139, 184, 279, 169.1, 169.2, 170.2; 422/224, 225, 99; 604/82; 60/69, 93, 94

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 4,711,582 (KENNEDY) 08 DECEMBER 1987.	1-18
A	US,A, 4,721,390 (LIDGREN) 26 JANUARY 1988.	1-18
A	US,A, 4,854,716 (ZIEMANN ET AL) 08 AUGUST 1989.	1-18

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Further documents are listed in the continuation of Box C.

☐

See patent family annex.

•	Special categories of cited documents:	•T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
•A	document defining the general state of the art which is not considered to be of particular relevance	•X	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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•P	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

02 JULY 1996

Date of mailing of the international search report

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